DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 6, 2015

NOVASTEP
Mr. Gilles Audic
QA/RA Director
Espace Performance Alphasis – Batiment C1-C2
35769 Saint Gregoire
France

Re: K143229
Trade/Device Name: Nexis® osteosynthesis compressive screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 20, 2014
Received: November 24, 2014

Dear Mr. Audic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section

4: Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143229

Device Name
Nexis® osteosynthesis compressive screws

Indications for Use *(Describe)*
The Nexis® osteosynthesis compressive screws are single use devices indicated for the fixing and stabilizing the elective osteotomies of the mid foot bones and the metatarsal and phalanges of the foot only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"510(k) Summary" as required by section 807.92(c)

Submitter	NOVASTEP Espace performance Alphasis Bâtiment C1-C2 35769 SAINT GREGOIRE France Phone : + 33 (0)2 99 33 86 50 Fax :+ 33 (0)9 70 29 18 95
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Preparation date	January 27th, 2015

Trade name	Nexis® osteosynthesis compressive screws
Common Name	Screw, Fixation, Bone
Classification Name	Smooth or threaded metallic fixation fastener (21CFR 888.3040, product code HWC)
Regulatory class	II

Legally marketed predicate devices	510(k) number: K070039 Device name: Memometal Fixos screws Original applicant: MEMOMETAL TECHNOLOGIES This predicate has not been subject to a design-related recall. 510(k) number: K052576 Device name: SBI Autofix™ System

	Original applicant: Small Bone Innovations International S.A. This predicate has not been subject to a design-related recall.
Description	Nexis® osteosynthesis compressive screws are single-use bone fixation devices intended to be permanently implanted. Nexis® osteosynthesis compressive screws are canulated compressive screws made of Titanium (Alloy Ti-6Al-4V ELI). Nexis® osteosynthesis compressive screws are compressive canulated bone screws which allow a permanent compression, thus supporting a secure osseous restoration.
Intended use	The Nexis® osteosynthesis compressive screws are intended for fixing and stabilizing the elective osteotomies of the mid-foot bones and metatarsal and phalanges of the foot only.
Comparison of the technological characteristics with the predicate device	The new devices Nexis® osteosynthesis compressive screws have similar technological characteristics in terms of material (ISO 5832-3 Implants For Surgery -- Metallic Materials -- Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy) and mechanical characteristics (ASTM F543-13 Standard Specification and Test Methods for Metallic Medical Bone Screws) and thus are believed to be substantially equivalent to the predicate Memometal Fixos screws (device references: S-Fix/C-Fix/P-Fix) (K070039) and SBI Autofix™ System (K052576).
Performance data	The biocompatibility evaluation for new devices Nexis® osteosynthesis compressive screws was conducted in accordance with Blue Book Memorandum #G95-1 (Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing) and International Standard ISO 10993-1 (Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process) as recognized by FDA. The new devices Nexis® osteosynthesis compressive screws have similar technological characteristics in terms of design and mechanical characteristics (Driving and removal torque, pull-out strength, torsional resistance) and thus are believed to be substantially equivalent to the predicate Memometal Fixos screws (device references: S-Fix/C-Fix/P-Fix) (K070039) and SBI Autofix™ System (K052576).
Indication for use	The Nexis® osteosynthesis compressive screws are indicated for fixing and stabilizing the elective osteotomies of the mid-foot bones and metatarsal and phalanges of the foot only. The indication for use statement for the Nexis® osteosynthesis compressive screws is not strictly identical to the predicate devices; However, the difference do not alter the intended therapeutic use of the

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	device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and the predicate device have the same intended use for fixation, correction and stabilization of small bones in the foot.
Clinical studies	Clinical studies were not required for this submission.
Animal studies	Animal studies were not required for this submission.
Conclusion	Nexis® osteosynthesis compressive are substantially equivalent to their predicate devices Memometal Fixos screws (device references: S-Fix/C-Fix/P-Fix) (K070039) and SBI AutofixTM System (K052576), in terms of intended use and indications for use, material, design and function. Any minor differences between these devices do not raise new questions of safety and effectiveness.

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